



THOMAS L. GARTHWAITE, M.D.
Director and Chief Medical Officer

FRED LEAF
Chief Operating Officer

COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES
313 N. Figueroa Street, Los Angeles, CA 90012
(213) 240-8101

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January 22, 2003

TO: Each Supervisor

FROM: Thomas L. Garthwaite, M.D., Director
and Chief Medical Officer
Department of Health Services

A handwritten signature in blue ink, which appears to read "Thomas L. Garthwaite", is written over the printed name and title.

**SUBJECT: RESPONSE TO THE JANUARY 14, 2003 BOARD MOTION
REGARDING THE ROLE OF THE RESEARCH OVERSIGHT
COMMITTEE**

This is in response to the Supervisor Burke's January 14, 2003 Board motion. As the Director of Health Services, I was instructed to report back to the Board on the role of the Research Oversight Committee in monitoring clinical research activities, with this report addressing the following issues:

1. The membership of the Department of Health Services Research Oversight Committee (ROC) and the system-wide Institutional Review Board (DHS IRB).

Initially, the ROC was composed of: the Medical Directors of the County Hospitals, as designees of the Chief Executive Officers of DHS Hospitals; selected members of the DHS IRB; and community members. Later, it was decided to substitute the more appropriate DHS Hospital IRB Chairpersons for the Medical Directors. Refer to Attachment I, the ROC Roster.

The DHS IRB is currently composed of eleven members with varying backgrounds, to adequately review the research activities conducted by DHS. There are representatives from major Program Offices, as well as from administration and the community. The IRB is sufficiently qualified through the experience and diversity of its members, to address sensitive issues such as community attitudes, vulnerable subjects, as well as regulations and standards of conduct and practice. The IRB is responsible for safeguarding the rights and welfare of human subjects. Refer to Attachment II, the IRB Roster.

2. The charter and mission of the Research Oversight Committee.

The ROC has responsibility for reviewing research projects from L.A. County's perspective, to ensure compliance with County precepts. The ROC brings proposals meeting defined selection criteria to the Department's attention. It is an independent committee, but has oversight responsibility for research projects previously reviewed by DHS and Hospital Institutional Review Boards. The ROC is responsible for ensuring that the rights and welfare of human subjects have been protected. Refer to Attachment III, the statement of ROC Procedures.

3. The relationship between the Research Oversight Committee and facility IRBs.

The ROC is an independent committee, and has oversight responsibility for research projects previously reviewed by the DHS and Hospital Institutional Review Boards. The membership of the ROC includes DHS Hospital IRB Chairpersons. The IRB Chairs are responsible for bringing hospital proposals that meet selection criteria to the ROC for review. Refer to Attachment III, the statement of ROC Procedures.

4. The mechanism for resolving human subjects protection issues that arise in research projects that have been approved by the facility IRBs.

The ROC reviews and has authority to approve, require modifications or disapprove research activities. The ROC notifies investigators in writing of its decision to approve or disapprove the proposed research activity. Stipulations from the ROC are sent to the IRB that initially approved the study. The stipulations must be addressed by the investigator through the approving IRB. The ROC will conduct continuing review of research when deemed necessary, at intervals appropriate to the degree of risk, but not less than once per year. Refer to Attachment III, the statement of ROC Procedures.

5. A summary of the findings and actions taken related to human subjects protection in the Department of Health Services physician research projects.

Attachment IV is the Annual Report for 2001-2002, indicating eight study protocols referred by the IRBs to the Research Oversight Committee.

If you have any questions or need additional information, please let me know.

TLG:jgh

Attachments

cc: Chief Administrative Officer
County Counsel
Executive Officer, Board of Supervisors

**COUNTY OF LOS ANGELES-DEPARTMENT OF HEALTH SERVICES
RESEARCH OVERSIGHT COMMITTEE MEMBERS**

ATTACHMENT

Marilyn Burke Community member	Los Angeles County-Public Health 313 N. Figueroa Street, Room 227 Los Angeles, CA 90012	(213) 240-8040 (213) 481-9853 FAX
I. Jean Davis, D.C., Ph.D. Community Member	P.O. Box 90818 Los Angeles, CA 90009	(310) 670-6084 (323) 564-9865 FAX
James G. Haughton, MD Medical Director, Public Health	Los Angeles County-Public Health 313 N. Figueroa Street, Room 227 Los Angeles, CA 90012	(213) 250-8685 (213) 481-9853 FAX
John Hoh, MD Community Member	Asian Pacific Health Care Venture 1530 Hillhurst Ave., 2nd. Floor Hollywood, CA 90027	(323) 644-3880 X 13 (323) 644-3892 FAX
Steward Laidlaw, PhD, Vice-Chair, Institutional Review Board	Harbor UCLA Institutional Review Board Office of Compliance and Regulatory Affairs	(310) 222-3624 (310) 320-6515 FAX
Donzella Lee, MPH Community member	T.H. E. Clinic 3860 W. Martin Luther King Blvd. Los Angeles, CA 90008	(323) 295-6571 X 3007 (323) 295-6577 FAX
Gerrie Rosen, Psy.D. Community member	African Community Resource Center, Inc. 532 So. Vermont Los Angeles, CA 90020	(213) 637-1450 (213) 382-6166 FAX
Anthony Shaw, MD, Chairman, Human subjects Protection	Olive View UCLA Education Research Institute, 218 Laboratory building	(818) 364-3434 (818) 364-3465 FAX
Darcy Spicer, MD, Vice Chair, Institutional Review Board	LAC+USC Medical Center Institutional Review Board 1200 N. Street, Trailer #25 Los Angeles, Ca 90033	(323) 223-2340 (323) 764-0061 FAX
Charles Stark, Pharm.D. Community member	Pfizer Inc. 2441 S. Gaffey Street San Pedro, CA 90731	(310) 547-1133 (310) 547-1123 FAX
Charles Stewart, MD, Chairman, Institutional Review Board Los Amigos Research & Education Institute Rancho Los Amigos National Rehabilitation center	Los Amigos Research & Education Institute Rancho Los Amigos National Rehabilitation center 7601 E. Imperial Hgwy., Bldg. 100- Room 027 Downey, CA 90242	(562) 401-7542 (562) 401-8353 FAX
Kenneth Wolf, Chairman, Institutional Review Board Charles Drew University	Charles Drew University 1731 E. 120th Street Los Angeles, CA 90059	(310) 668-4536 (310) 668-4555 FAX

**LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
INSTITUTIONAL REVIEW BOARD
DIRECTORY**

ATTACHMENT II

Name	Address	Telephone	FAX	E-mail address
Benita Coucil, Pharm.D. United Pharmacist Network Inc.	United Pharmacist Network Inc. 3837 ½ Santa Rosalia Los Angeles, CA 90008	(323) 778-5464	(323) 295-1986	
I. Jean Davis, D.C., Ph.D. Community Member	King Drew Medical Center P.O. Box 90818 Los Angeles, CA 90009	(310) 670-6084	(310) 673-8929	
Howard Ross Jacobs Community Member	1125 ½ N. Ogden Dr. West Hollywood, CA 90046	323 650-1979		
Anna Long, PhD,, MPH Wesley Ford (alternate)	Los Angeles County, Department of Health Services Public Health Programs & Services 313 N. Figueroa St., Room 806 Los Angeles, CA 90012	(213) 240-8117	(213) 975-1273	
James G. Haughton, MD,MPH Medical Director, PHP&S Chair, DHS-IRB Vice Chair: Paul Simon,MD, MPH	Los Angeles County Department of Health Services Public Health Programs & Services 313 N. Figueroa St., Room 227 Los Angeles, CA 90012	(213) 250-8685	(213) 481-9853	jhaughton@dhs.co.la.ca.us
Susan Partridge, RN, MBA Administrator, UCLA Center for Vaccine Research Harbor-UCLA Research & Education Institute Assistant Professor Pediatrics UCLA School of Medicine	Harbor-UCLA Medical Center 1124 W. Carson Street, Bldg. RB-3 Torrance, CA 90502	(310) 781-3636	(310) 782-8776	partridge@humc.edu
Rob. Hurd Settlege, MD,MPH Medical Director Maternal Health & Family Planning	Los Angeles County Department of Health Services 600 S. Commonwealth Ave #800 Los Angeles, CA 90005-4001	(213) 639-6416	(213) 639-1034	rsettlag@eagle.co.laca.us

**LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
INSTITUTIONAL REVIEW BOARD
DIRECTORY**

Name	Address	Telephone	FAX	E-mail address
Paul A. Simon, MD, MPH Chief, Office of Health Assessment and Epidemiology, LAC-DHS Vice Chair, DHS-IRB Alternate: Marc Strassburg, Dr. P.H.	Los Angeles County Department of Health Services Office of Health Assessment and Epidemiology, PHP&S 313 N. Figueroa Street, Rm. 127 Los Angeles, CA 90012	(213) 240-7785	(213) 250-2594	psimon@dhs.co.la.ca.us
Walton Senterfitt, PhD	Los Angeles County Department of Health Services Office of Health Assessment and Epidemiology, PHP&S 313 N. Figueroa Street, Rm. 127 Los Angeles, CA 90012	(213) 240-7785	(213) 250-2594	
Ron Snyder community Member/Prisoner Advocate	17830 Sherman Way #163 Reseda, CA 91335	818 705-7352		
Christine Wigen, MD Alternate: Rochaun Smith	Los Angeles County Department of Health Services TB Control 2615 S. Grant Ave, Suite 500 Los Angeles, CA 90007	(213) 744-6254		

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RESEARCH OVERSIGHT COMMITTEE-PROCEDURES

The Research Oversight Committee (ROC) has responsibility for reviewing research projects from L.A. County's perspective to ensure compliance with County precepts. The ROC will bring proposals meeting defined selection criteria to the Department's attention. It is an independent committee, but only has oversight responsibility for research projects previously reviewed by existing Institutional Review Boards.

The Research Oversight Committee shall be composed of selected members of the DHS IRB, the Chief Executive Officers of all DHS hospitals or their designees (preferably the Medical Directors of the hospitals) and community members. The ROC has been designated to review research projects previously reviewed by existing Institutional Review Boards. The following organizations have IRBs that approve research requiring ROC review as the use of County patients and/or execution in DHS facilities is proposed:

DHS Institutional Review Board.
Rancho Los Amigos Research and Education Institute.
Harbor/UCLA Research and Education Institute.
USC Health Research Association.
Drew Foundation for Medical Research.
Olive View Education Research Institute.

The Chief Executive Officers of all DHS hospitals or their designees shall be assigned the responsibility for bringing proposals to the ROC for review. The following selection criteria for proposals forwarded for ROC review must be applied to all research proposals being reviewed by existing IRBs proposing to utilize County patients and/or specifying execution in a County facility:

- A. Proposals which are approved by an IRB with dissenting votes occasioned by concerns related to the protection of human subjects.
- B. Proposals which involve community sensitivities.
- C. Proposals which present high risks and minimal benefits to the human subjects of the research.
- D. Proposals which include the use of County resources without adequate reimbursement from the research grant.
- E. Proposals which are high profile and likely to attract adverse press and/or media attention.
- F. Proposals which request waiver of consent.
- G. Proposals involving human subjects who are members of a vulnerable group, such as children or prisoners.

The ROC shall review and has authority to approve, require modifications or disapprove research activities. The ROC shall notify Investigators in writing of its decision to approve or disapprove the proposed research activity (Attached letter). The Investigator

must be notified in a timely manner when changes have been recommended by the ROC. Stipulations from the ROC will be sent to the IRB that initially approved the study. The stipulations must be addressed by the Investigator through the approving IRB. The ROC shall conduct continuing review of research when deemed necessary, at intervals appropriate to the degree of risk, but not less than once per year. (The existing IRBs that reviewed the initial proposals are required to conduct their continuing reviews).

Review Category:

RESEARCH OVERSIGHT COMMITTEE
COUNTY OF LOS ANGELES - DEPARTMENT OF HEALTH SERVICES

Date:

To:

From:

TITLE OF PROPOSAL:

Date:

Action taken

C ttee. DHS Research Oversight Committee



COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES
Public Health

THOMAS L. GARTHWAITE, M.D.
Director of Health Services and Chief Medical Officer

JONATHAN E. FIELDING, M.D., M.P.H.
Director of Public Health and Health Officer

Office of Public Health Medical Director

JAMES G. HAUGHTON, M.D., M.P.H., F.A.C.P.M., Medical Director
313 North Figueroa Street, Room 227
Los Angeles, California 90012
TEL (213) 250-8685 • FAX (213) 481-9853

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Fifth District

October 9, 2002

TO: Research Oversight Committee

FROM: James G. Haughton, MD, MPH
Chairman, DHS Institutional Review Board

SUBJECT: **ANNUAL REPORT OF THE 2001-2002 IRB(S)**

The IRB(s) and the institution operate under: MPA or FWA number with the Office of Protection from Research Risks: **DHS Institutional Review Board FWA No. IORG0000533 - IRB00000864**

During the 2001-2002 fiscal year:

New or continuing research protocols reviewed: 43 DHS IRB reviewed

New or continuing research protocols disapproved or terminated 11 studies reported to the DHS IRB and noted completed or closed to accrual.

New or continuing research protocols meeting the federal criteria for exemption from review: 4

Number of individuals trained in the protection of human subjects: 76 (18 DHS IRB members, 58 DHS Research Investigators including research project staff involved).

Training consists of: Understanding the Fundamentals; Responsibilities and requirements for the Protection of Human Subjects in Research;"
"Protecting Study Volunteers in Research"

Training is verified by: **Marilyn Burke**

Ongoing trainings is assured by: **James G. Haughton, MD, MPH**

The IRB(s) have referred 8 protocols to the ROC in FY 2001-2002.

The IRB(s)/Compliance support office have reviewed and updated their policies and procedures (Date of last review): 10/24/02

We have reviewed and updated our research review protocols and are in compliance with Federal regulations.

Our next annual report will be provided to the Board within 60 days of the end of the current fiscal year.

October 28, 2002

TO: Research Oversight Committee

FROM: Stewart A. Laidlaw, Ph.D.
Director, Compliance & Regulatory Affairs
Harbor-UCLA Research and Education Institute

SUBJECT: *ANNUAL REPORT OF THE JOHN F. WOLF, MD HUMAN SUBJECTS
COMMITTEES (1 AND 2) AT THE RESEARCH AND EDUCATION INSTITUTE
OF THE HARBOR-UCLA MEDICAL CENTER*

The IRB(s) and the institution operate under FWA00001992 and FWA00002334 with the Office of Human Research Protection.

During the 2001-2002 fiscal year:

New and continuing research protocols reviewed: 707

New and continuing research protocols disapproved or terminated: 5

New and continuing research protocols meeting the federal criteria for exemption from review:
49

Number of individuals trained in the protection of human subjects: 1067 (since initiation of training in August 2000).

Training consists of: Passing a 50-question multiple choice test with a score of 85% or better (test can be taken with or without study materials that include the "Protecting Study Volunteers in Research" book or videotape of the lecture of the same title).

Training is verified by: Database and issuance of certificate

Ongoing training is assured by: Responsible Conduct in Research Course (mandatory for all research key personnel). This course offers four main core units twice a year and continuing education units once a year. At least one continuing education unit must be taken per year after completion of main core units. Completion of main core units is mandatory by December 2003 for all key personnel.

The IRB(s) have referred 5 protocols to the ROC in FY 2001-2002.

The IRB(s)/Compliance support office have reviewed and updated their policies and procedures August 2002.

We have reviewed and updated our research review protocols and are in compliance with Federal regulations.

Our next annual report will be provided to the Board within 60 days of the end of the current fiscal year.

TO: Research Oversight Committee

FROM Kenneth E. Wolf, Ph.D.

SUBJECT: ANNUAL REPORT OF
THE Charles R. Drew University of Medicine and Science IRB(s)

The IRB(s) and the institution operate under: FWA 00002736 & FWA 00002789 with the Office of Human Research Protection.

During the 2001-2002 fiscal year:

New or continuing research protocols reviewed: 91

New or continuing research protocols disapproved or terminated: 6

New or continuing research protocols meeting the federal criteria for exemption from review :
36

Number of individuals trained in the protection of human subjects: 494

Training consists of: UCLA Online "Protection Human Research Subjects" Course

Training is verified by: Receipt of Printed Certificate of Completion

Ongoing training is assured by:

The IRB(s) have referred 1 protocol to the ROC in FY 2001-2002.

The IRB(s)/Compliance support office have reviewed and updated their policies and procedures monthly by IRB systematically review all forms and chapters in IRB Manual.

We have reviewed and updated our research review protocols and are in compliance with Federal regulations.

Our next annual report will be provided to the Board within 60 days of the end of the current fiscal year.

October 28, 2002

TO: Research Oversight Committee

FROM: Diana Shycoff, Director
IRB Office

SUBJECT: Annual Report of the University of Southern California Health Sciences Campus,
LAC+USC Healthcare Network and Health Research Association IRB

The IRB and the institution operate under MPA-1372-01 with the Office of Human Research Protection.

During the 2001-2002 fiscal year:

New research protocols undergoing full board review: 427

New research protocols which were reviewed but not approved during fiscal year 2001-2002: 17

New research protocols meeting the federal criteria for expedited review or were deemed exempt from review: 254

Number of individuals trained in the protection of human subjects: 1,598

Training consists of: Completion of the IRB Education sessions, IRB member education conducted at convened meetings, coordinator meetings, and attendance at Human Subjects Protection Conferences/meetings

Training is verified by the IRB Office, USC Office of Compliance, and USC Contracts and Grants Office.

Ongoing training is assured by the USC Office of Compliance and IRB Office.

The IRB has not referred any protocols to the ROC in FY 2001-2002.

The IRB Office has reviewed and updated our policies and procedures dated 9/18/02.

We have reviewed and updated our research review protocols and are in compliance with Federal regulations.

Our next annual report will be provided to the Board within 60 days of the end of the current fiscal year.

TO: Research Oversight Committee

FROM: Anthony Shaw, M.D.

SUBJECT: ANNUAL REPORT OF THE Olive View-UCLA Education & Research Institute
IRB(s)

The IRB(s) and the institution operate under: (MPA or FWA number) with the Office of Human
Research Protection FWA 00000495 - IRB 00000669

During the 2001-2002 fiscal year:

New or continuing research protocols reviewed: (New Projects-35/Renewals 59)

New or continuing research protocols disapproved or terminated: 49

New or continuing research protocols meeting the federal criteria for exemption from review :
10_

Number of individuals trained in the protection of human subjects: 10*

*this number does not include individuals trained at other institutions, e.g. UCLA

Training consists of: Distribution of training manual followed by test.

Training is verified by: IRB Administration

Ongoing training is assured by: IRB Administration

The IRB(s) have referred _0_ protocols to the ROC in FY 2001-2002.

The IRB(s)/Compliance support office have reviewed and updated their policies and procedures
July 1, 2002

We have reviewed and updated our research review protocols and are in compliance with
Federal regulations.

Our next annual report will be provided to the Board within 60 days of the end of the current
fiscal year.

TO: Research Oversight Committee

FROM: Charles A. Stewart, M.D.

SUBJECT: ANNUAL REPORT OF THE Los Amigos Research and Education Institute, Inc.
IRB

The IRB and the institution operate under: FWA number 00002950 with the Office for Human Research Protections.

During the 2001-2002 fiscal year:

New or continuing research protocols reviewed and approved: 90.

New or continuing research protocols disapproved or terminated: 28.

New or continuing research protocols meeting the federal criteria for exemption from review 10.

Number of individuals trained in the protection of human subjects: 129.

Training consists of: A 90-minute video presentation with discussions was held on 11/14/01 on "Protecting Human Subjects in Research". Participants received hand out material with a test. Upon successful completion of the test, a certificate was issued. Individuals who could not attend the meeting, or who started research projects at a later date are sent the information packet with the questionnaire to be completed before they can start on a research project.

Training is verified by: The IRB Chair.

Ongoing training is assured by: The Administrative Officer of Los Amigos Research and Education Institute, Inc.

The IRB has referred 4 protocols to the ROC in FY 2001-2002.

The IRB/Compliance support office has reviewed and updated their policies and procedures. A rough draft was prepared in October 2002 and is pending review by the IRB.

We have reviewed and updated our research review protocols and are in compliance with Federal regulations.

Our next annual report will be provided to the Board within 60 days of the end of the current fiscal year.



RESEARCH & EDUCATION
INSTITUTE
at HARBOR-UCLA
MEDICAL CENTER

Stewart A. Laidlaw, Ph.D.
Director of Compliance & Educational Outreach
Professor of Medicine/Academic Administrator

November 18, 2002

Thomas Garthwaite, M.D.
Director and Chief Medical Officer
Department of Health Services
County of Los Angeles
313 N. Figueroa
Los Angeles
CA 90012

Dear Dr. Garthwaite:

Attached please find the annual reports of the Institutional Review Boards of the hospitals and clinics of the Department of Health Services of L.A. County. These reports are submitted in fulfillment of the requirements of the County Board of Supervisors to assure the Board that the human subjects research conducted in county facilities is being done according to the requirements of federal, state and local regulations for the protection of human study volunteers. I apologize for the delay in submitting these reports this year. As you may recall, the Research Oversight Committee was significantly reorganized over the past six months with new membership. This led to some delay in meeting the requirement for submitting the annual reports.

If there is any additional information you need, please feel free to contact me at (310) 222 3624 or by e-mail at slaidlaw@rei.edu. Let me also take this opportunity to thank you for your confidence in me by appointing me as your proxy as Chair of the Research Oversight Committee.

Sincerely,

Stewart A. Laidlaw, Ph.D.
Chair, Research Oversight Committee
Harbor-UCLA REI.

Cc: Chairs, DHS IRB's

Attachment: Annual Reports



MINUTES OF THE BOARD
COUNTY OF LOS ANGELES

Violet Varona-Luh
Clerk of the Board
383 Kenneth Hall
Los Angeles, Calif.

Director of Health Services

Per our telephone conversation, see the attached motion. As I was informed, the Research Oversight Committee (Dr. Houghton) should have prepared a report for Burke's office. The supervisor's office is requesting the report.

Please follow up w/ program office and let me know of the status.

Thanks

Stella
1/16/03

41-1853

At its meeting held October 8, 2002, the Board took the following action:

5

Supervisor Burke made the following statement:

"In 1998, in response to problems associated with protecting patients involved in a clinical research trial, the Board directed the Director of Health Services to closely evaluate the research protocols that exist across the system to protect patients, as well as to strengthen the monitoring of research activities in the County's health services facilities.

"In response, the Department established a Research Oversight Committee to monitor the research activities conducted in our facilities, as well as in Public Health. This was to include reviewing research protocols and ensuring that clinical staff involved in the research project adhered to these standards.

"The Research Oversight Committee was to play a leadership role in the Department to ensure that there was strict adherence to protocols and patient protections, provide education and support to facility Institutional Review Boards to prevent violations, and to ensure ongoing communication with the community on the impact and value of the research being conducted. This Committee was established to serve as an independent arbiter of the County's research activities.

"The Research Oversight Committee has been in place now for several years, which should have allowed the Department to collect significant information about the compliance of clinical research with human subjects protocols. I think it is important for the Board to be informed about what steps the Department of Health Services has taken to ensure patients are protected in the course of research activities and what the experience is in complying with human subjects protections."

Therefore, on motion of Supervisor Burke, seconded by Supervisor Molina, unanimously carried, the Director of Health Services was instructed to report back to the Board within 30 days on the role played by the Research Oversight Committee in monitoring clinical research activities, with the report to address the following issues:

1. The membership of the Department of Health Services Oversight Committee and the System-wide Institutional Research Board (IRB);
2. The charter and mission of the Research Oversight Committee;
3. The relationship between the Research Oversight Committee and facility IRBs;
4. The mechanism for resolving human subjects protection issues that arise in research projects that have been approved by the facility IRBs; and
5. A summary of the findings and actions taken related to human subjects protection in the Department of Health Services physician research projects.

7100802-5

Copies distributed:

Each Supervisor
Chief Administrative Officer
County Counsel



MINUTES OF THE BOARD
COUNTY OF LOS ANGELES

Violet Varona-Luh
Clerk of the Board
383 Kenneth Hall
Los Angeles, Calif.

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Stella
1/16/03

487-1123

Director of Health Services

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"The Research Oversight Committee was to play a leadership role in the Department to ensure that there was strict adherence to protocols and patient protections, provide education and support to facility Institutional Review Boards to prevent violations, and to ensure ongoing communication with the community on the impact and value of the research being conducted. This Committee was established to serve as an independent arbiter of the County's research activities.

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Chief Administrative Officer

http://bos.co.la.ca.us/SOP_Final_Act/7100802-5.HTM

1. The membership of the Department of Health Services Oversight Committee and the System-wide Institutional Research Board (IRB);
2. The charter and mission of the Research Oversight Committee;
3. The relationship between the Research Oversight Committee and facility IRBs;
4. The mechanism for resolving human subjects protection issues that arise in research projects that have been approved by the facility IRBs; and
5. A summary of the findings and actions taken related to human subjects protection in the Department of Health Services physician research projects.

7100802-5

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